Supreme Court, U.S.
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No. 91-1987

In The

Supreme Court of the United States

October Term, 1992

GARY TURPIN and BETTY TURPIN
Individually and as Parent and Natural
Guardian of BRANDY TURPIN, a Minor,

Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,

Respondent.

Petition For Writ Of Certiorari
To The United States Court Of Appeals
For The Sixth Circuit

BRIEF FOR RESPONDENT MERRELL DOW PHARMACEUTICALS, INC. IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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August 7, 1992

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CORPORATE AFFILIATIONS OF RESPONDENT

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INTRODUCTION

Four times in the past two years this Court has been asked to grant *certiorari* to determine the quantum of evidence required before a Bendectin plaintiff meets her burden of proof requiring submission of her case to a jury. Four times this Court has denied those petitions.[1] Here, in the fifth such instance, Petitioners ask this Court to revisit long settled issues. Petitioners' claims notwithstanding, this case presents no new issue worthy of review, but only a fact specific application of established summary judgment standards and the determination that Petitioners' evidence failed to raise a genuine issue of material fact. Contrary to Petitioners' assertions, this case involves neither an attempt to impose a nationwide uniformity on scientific issues to prevent inconsistent verdicts, nor an attempt by the judiciary to preclude resolution of future cases on the merits.

In seeking to contrive a meaty issue to review, Petitioners ignore the distinction between admissibility of evidence and the sufficiency of that evidence to prove a particular fact. Petitioners argue that, where an expert's opinion is admissible, that opinion is, perforce and as a matter of federal law, enough to prove the fact opined. However it may be burdened with words, Petitioners real point is quite simple and easily paraphrased. Petitioners maintain that a federal court can *never* grant summary judgment against the opinion of any expert regardless of the

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[1] *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 110 S.Ct. 1511 (1990); *Koller v. Richardson-Merrell, Inc.*, 111 S.Ct. 1391 (1991); *Richardson v. Richardson-Merrell, Inc.*, 110 S.Ct. 218 (1989); *Ealy v. Richardson-Merrell, Inc.*, 111 S.Ct. 370 (1990).

weight of logic or evidence arrayed against such opinion, i.e., any admissible expert opinion precludes summary judgment. Petitioners' formulation of the "Questions Presented" in their petition neatly begs the real legal question of the case.

To secure reversal of the district court's ruling that they failed to present evidence sufficient to warrant a jury trial, Petitioners now ask this Court to define sufficiency to fit their evidence. However, the only rule of general utility to the federal courts which this Court could formulate to oblige the Petitioners would be that *any* admissible expert opinions will *always* defeat a motion for summary judgment on the fact opined. Such a standard for summary judgment is not – and should not become – the law.

This case presents no conflict among the circuits. This case presents only a failure of a particular plaintiff to produce evidence sufficient to overcome a well pled motion for summary judgment. For these reasons, and those set forth below, the instant petition should be denied.

COUNTER-STATEMENT OF THE CASE

Petitioners' Statement of the Case embellishes the district court's express analysis of the record. Petitioners' Statement of the Case includes their impressions as to how the lower courts interpreted affidavits submitted on the issues presented by Respondents' motion for summary judgment. These impressions are not found anywhere within the record before this Court. Accordingly,

Respondent will, in this Counterstatement, describe the lower court's analysis of the record in this case as well as the documented record concerning Bendectin.

THE LOWER COURTS' ANALYSIS OF THE RECORD IN THIS CASE

Merrell Dow Pharmaceuticals Inc. ("Merrell Dow") manufactured and marketed Bendectin from 1956 to 1983. Bendectin was an anti-nauseant, available only by prescription, for use by pregnant women to treat "morning sickness," the nausea and vomiting frequently associated with pregnancy.

The leading treatment for morning sickness, Bendectin was prescribed in as many as 25% to 30% of all United States pregnancies. An estimated 33 million women world-wide took Bendectin during pregnancy. This broad and long term use of the product combined with the common occurrence of birth defects in the general population, assured, merely as a matter of background incidence, that many women who had taken Bendectin would bear children with birth defects. These events spawned a monumental tort litigation.[2] Because of enormous litigation costs, Merrell Dow ceased producing Bendectin in 1983, despite the fact that it was, and still is,

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[2] *Sheffield*, et al., "The Creation of Therapeutic Orphans – or What Have We Learnt From The Debendox Fiasco," 143 *Med. J. Australia* 143 (1985). In Australia and England, Bendectin was known as Debendox.

approved for marketing by the Food and Drug Administration.[3]

In 1984, Plaintiffs filed this action alleging that Betty Turpin's use of Bendectin while pregnant with her daughter Brandy in 1981, caused Brandy Turpin to be born with limb reduction defects of her hands and feet.[4] After extensive discovery, Merrell Dow moved for summary judgment on two grounds, first, Plaintiffs' experts' testimony was inadmissible under Rule 703, Federal Rules of Evidence, because these opinions were based upon information and data not reasonably relied upon by experts in the field. Second, even if such opinions were admissible, they were insufficient to allow a reasonable trier of fact to conclude that Bendectin caused Brandy Turpin's birth defects. Merrell Dow supported its motion with "35 human epidemiological studies supporting a finding that the use of Bendectin does not cause birth defects," (A 8)[5]

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[3] In 1980, the FDA's Fertility and Maternal Health Drugs Advisory Committee, after studying the relevant literature and conducting a full hearing on the issue, concluded that "there was no increased incidence of birth defects among Bendectin-exposed infants; that there was no need for further animal or epidemiological studies; and that Bendectin should not be withdrawn from the market." The FDA adopted these findings, and to this day, continues its approval of Bendectin. *See, Richardson v. Richardson-Merrell Inc.*, 857 F.2d 823, 824, 827 (D.C. Cir. 1988), *cert. denied*, 110 S. Ct. 218 (1989).

[4] An agent or influence which causes physical defects in the developing embryo is called a teratogen. *Dorland's Medical Dictionary, Shorter Edition* 658 (1980).

[5] Petitioners' Appendix A is incorporated by reference herein. Unless otherwise indicated all record cites are to Petitioners' Appendix.

and the affidavits of three experts who opined that Bendectin does not cause birth defects.[6]

In response, Plaintiffs submitted the affidavits of seven "expert" witnesses, only one of whom concluded that Bendectin caused Brandy's limb defects.[7] These experts reached their opinions by considering four types of data – 1) *in vivo*, or live animal studies 2) *in vitro* animal studies, 3) studies of analogous chemical structures, and 4) reanalyses and criticisms of various epidemiological studies relied upon and submitted by Merrell Dow. Plaintiffs further erroneously argued that the methodology used by their experts in assessing the value of this kind of evidence was not disputed – only their conclusions. Accordingly, Plaintiffs contended that their experts' testimony was indeed admissible and presented a jury issue.

On April 25, 1990, after reviewing "the voluminous materials submitted by the parties," the district court granted Merrell Dow's motion for summary judgment. (A 23.) The district court measured Plaintiffs' expert testimony against the Sixth Circuit's test for admissibility as set forth in *United States v. Kozminski*, 821 F.2d 1186, 1194 (6th Cir. 1987), *aff'd*, 487 U.S. 931 (1988) (A 27.) Judged by this yardstick, Plaintiffs' experts' testimony was found "not in conformity with a generally accepted explanatory

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[6] Two affiants, Steven H. Lamm, M.D. and Bryan D. Hall, M.D., specifically concluded that Bendectin did not cause Brandy Turpin's birth defects.

[7] The remaining affidavits were copies of those filed in other cases. (A 29, 32.)

theory" and, therefore, inadmissible under rule 703.[8] (A 27, 34, 35.) The district court further held that, even if such testimony was admissible, it was insufficient to allow a jury to find causation. " . . . [T]hese opinions only support the conclusion that it is possible that Bendectin is teratogenic, and not more likely or probable than not that a causal relationship exists. . . . " (A 35.)

The Sixth Circuit Court of Appeals affirmed the district court's judgment, observing that "courts have a duty to inspect the reasoning of qualified scientific experts to determine whether a case should go to the jury." (A 1-2.) The Court *assumed*, without so ruling, that Plaintiffs' proffered testimony was admissible,[9] and concluded that this case "should be decided on the rules of the sufficiency of evidence of causation." (A 7.) After full review, the Sixth Circuit affirmed the district court's ruling that Plaintiffs' evidence was insufficient basis for a reasonable jury to conclude that there is a causal connection between Bendectin and Brandy Turpin's birth defects.

The court first reviewed the epidemiological evidence offered by Merrell Dow and reanalyzed by Plaintiffs' experts:

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[8] In applying the test for admissibility while reviewing the bases of the expert's opinion, the district court was deciding matters of law. (A 27.)

[9] Should this Court determine that *certiorari* is warranted, and upon review, reverse the Sixth Circuit, a remand thereto is necessary to allow that Court to rule upon the district court's primary finding that Plaintiffs' evidence was inadmissible. A remand is necessary because this issue has not been preserved by Petitioners' for review by this Court.

> Although we agree with the defendant that its epidemiological studies and Dr. Lamm's testimony constitute evidence on which a jury might grant a defendant's verdict, we agree with plaintiffs' experts that this evidence is by no means conclusive.
>
> * * *
>
> The science of epidemiology is currently unable to identify the causes of many birth defects or to exclude from consideration many possible causes, including Bendectin and a host of other outside agents and environmental factors.

(A 16.)

In similar fashion, the court reviewed the other components of plaintiffs' evidence and found them incapable of raising a genuine issue on causation. Dr. Newman, one of Plaintiffs' experts, relied on *in vitro* studies, "experiments on embryonic cells in petri dishes . . . . [where] [l]imb-forming cells are removed from the embryo . . . and are isolated in a dish, where selected cells are treated with a suspected teratogen." He could "only testify that these chemical compounds connected with Bendectin are 'capable of causing' limb defects in humans, not that they do cause such defects." (A 17-18.)

In vivo studies are "experiments [where] suspected teratogens are administered to pregnant female animals. Shortly before their birth, the infants are removed from their mother and studied for defects." (A 18.) Dr. Gross, another of Plaintiffs' experts, "gave his opinion that doxyalamine [sic] succinate in Bendectin has the 'capacity' to interfere with human cell development at normal dosages

but could not testify that it does cause such defects." (A 19.)

Because these experts were only able to say that Bendectin was "capable" of causing birth defects, the court held that "the scientific opinions . . . will not support a finding that Bendectin more probably than not caused the birth defect here, . . . because [the experts] testify to a possibility rather than a probability." (A 20.)[10]

Only one of Plaintiffs' experts, Dr. Palmer, expressed the view in his affidavit that Bendectin caused Brandy Turpin's defects. The court independently reviewed this testimony and observed that Dr. Palmer relied upon the same evidence as Plaintiffs' other experts. Based upon this evidence, Dr. Palmer testified that Bendectin has "teratogenic properties," and that Bendectin caused Brandy Turpin's birth defects. In making this quantum leap, Dr. Palmer provided no additional bases to support his conclusion:

> Dr. Palmer does not testify on the basis of the collective view of his scientific discipline, nor does he take issue with his peers and explain the grounds for his differences. Indeed, no understandable scientific basis is stated . . . . Dr. Palmer's own expressed skepticism as to the value of extrapolating human conclusions from animal studies further confounds the issue. Upon analysis, we conclude that Dr. Palmer's

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[10] "The weakness of plaintiffs' case results from the care with which reputable scientists use animal experiments to predict causation in humans. This weakness arises from the fact that different species of animals react differently to the same stimuli for reasons not entirely understood." (A 19).

> conclusions go far beyond the known facts that form the premise for the conclusion stated. This conclusion so overstates its predicate that we hold that it cannot legitimately form the basis for a jury verdict.

(A 21.) Because Dr. Palmer's opinion went far beyond those supplied by other experts for the Plaintiffs but relied upon no additional evidence, the court concluded that "personal opinion, not science" was testifying. (*Id.*) Thus, "the evidence cited in support of his conclusion [was] insufficient to meet Plaintiffs' burden of proof." (A 21.)

ARGUMENT

1. This Court Should Deny Certiorari Because This Case Does Not Involve Any Conflict Between FRCP Rule 56 and FRE Rules 704 and 705.

Under Rule 56, Federal Rules of Civil Procedure, summary judgment is proper "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case and on which that party will have the burden of proof at trial." *Celotex Corporation v. Catrett*, 477 U.S. 317, 322 (1986). Once the moving party has demonstrated that there is no genuine issue of material fact, the non-moving party must come forward with "some significant probative evidence which makes it necessary to resolve the parties' differing versions of the dispute at trial." *60 Ivy Street Corporation v. Alexander*, 822 F.2d 1432, 1435 (6th Cir. 1987); *see also Matsushita Electric Industrial Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586-587, (1986); *Potters Medical Center v. City Hospital Association*, 800 F.2d 568, 572 (6th Cir. 1986).

The central question posed by any summary judgment motion is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-252 (1986). This standard asks, not whether *any* jury could find for the non-moving party, but rather whether there is "evidence on which the jury could *reasonably*" find for the non-moving party. *Id.* (emphasis added). This review by the trial court should not focus on individual pieces of evidence or isolated facts. Rather, the court is directed to grant summary judgment "[w]here the record taken as a *whole* could not lead a *rational* trier of fact to find for the non-moving party. . . . " *Matsushita*, 475 U.S. at 587 (emphasis added).

Rule 56 provides that a summary judgment is proper if the non-moving party is unable to come forward with sufficient evidence to enable a reasonable jury to find in favor of the non-movant on a material issue of fact. Rule 56(e) requires that, in order to defeat a well supported summary judgment motion, the non-movant must counter the motion with evidence sufficient to raise a genuine issue of material fact. Rule 56 does not prevent a party from opposing a motion for summary judgment with expert testimony in the form admissible under Rules 704 and 705. However, if evidence, expert or otherwise, fails to set forth specific facts *sufficient* to raise a genuine issue of material fact, it will not defeat a well pled motion for summary judgment.

In contrast to Rule 56, Rules 704 and 705 of the Federal Rules of Evidence address only the admissibility of expert testimony, not the sufficiency of any such evidence to support a party's case on any particular fact.

Rules 704(a) and 705 do no more than set forth the type and form of testimony which may be admitted into evidence. Rule 704(a) permits testimony, otherwise admissible, to "embrace an ultimate fact," and Rule 705 provides that an expert's opinion and reasons for that opinion are *admissible* without prior disclosure of the underlying basis of that opinion. Rule 56 is no more than a requirement by the Court that the expert set forth these "underlying facts and data." Rule 705 also prescribes that an expert may be required by the court to disclose the basis of any opinion admitted under Rule 705. Petitioners' argument that there is a conflict between Rule 56 and Rules 704 and 705 ignores this inherent distinction between admissibility and sufficiency of evidence and seeks to replace the sufficiency standard enunciated by this Court with a "mere presence of evidence" standard.

In this case, the Sixth Circuit did not rule on the admissibility of Petitioners' expert evidence but assumed *arguendo* that such would be admissible. This approach complied with FRE Rule 705 which provides for the admissibility of an expert's opinions and reasons for those opinions. (A 7.) The Circuit Court then judged the evidence against the summary judgment standard and held that, while Respondent's evidence was not conclusive, Petitioners' evidence failed to demonstrate more than a possibility that Bendectin caused Brandy Turpin's birth defect. (A 20-21.) The Circuit Court determined that Petitioners had failed to present sufficient evidence to allow a reasonable jury to find in their favor. In the absence of this threshold level of evidence, summary judgment was proper. *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986).

Contending that there is conflict among the circuits over the interaction of Rule 56 and Rules 704 and 705, Petitioners cite to several cases, none of which support their contention. In *Quinton v. Farmland Industries, Inc.*, 928 F.2d 335 (10th Cir. 1991), the court, on a motion for judgement notwithstanding the verdict, reviewed the basis of the expert's opinion to determine whether the opinion could support the jury verdict in favor of the plaintiff. The Tenth Circuit held that the particular expert testimony admitted there was sufficient to support the jury verdict and denied the motion. *Id.*, at 338. The Tenth Circuit did not hold, as Petitioners imply, that any expert testimony, *however implausible*, precludes any challenge to the sufficiency of evidence on a factual issue. Petition at 12. Petitioners' reliance on the cases of *United States v. A&S Council Oil Co.*, 947 F.2d 1128 (4th Cir. 1991) and *Smith v. Ford Motor Co.*, 626 F.2d 784 (10th Cir. 1980), *cert. denied*, 450 U.S. 918 (1981) is likewise misplaced, as these cases deal with the scope of pretrial discovery of an expert's opinions, their bases and the scope of cross examination at trial.

Petitioners' citation to opinions[11] of the D.C. Circuit, specifically, *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984) is puzzling. That same court in *Richardson v. Richardson-Merrell Inc.*, 857 F.2d 823 (D.C. Cir.1988), *cert. denied*, 110 S.Ct. 218

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[11] In *U.S. v. Wright*, 783 F.2d 1091 (D.C. Cir. 1986) which predates *Richardson*, the Court addressed the exception under FRE 703 which allows the admissibility of the basis of an expert's opinion even if that basis is in the form of otherwise inadmissible hearsay. *Id.*, at 1100-1101. The Court did not address the issue of the sufficiency of such opinion testimony under FRCP 56.

(1989), granted judgment notwithstanding the verdict for Respondent, and there distinguished *Ferebee* as limited to cases involving the "frontiers" of science and not those cases where, as here, a settled scientific consensus has been reached. *Id.* at 831-832. Most recently, in *Ambrosini v. Labarraque*, No.'s 90-7146, 7148, *slip op.* (D.C. Cir. June 12, 1992), 1992 W.L. 126340 (D.C. Cir. 1992),[12] this same court stated: "[t]his court, as well as others, has recognized that the issue of admissibility of an expert's opinion under Rule 703 and 705 is *separate* and *distinct* from the issue whether the testimony is sufficient to withstand a motion for summary judgment under Rule 56" (citations omitted, emphasis added). (B14.)

Petitioners' reading of *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3rd Cir. 1990) is simply incorrect. In *DeLuca*, the Third Circuit held that there was insufficient evidence in the record to support the district court's exclusion of plaintiff's expert testimony under FRE 703. *Id.* at 953. The Third Circuit, did *not*, as Petitioners suggest, hold that summary judgment was never proper when there is admissible expert testimony. In fact, the Third Circuit expressly acknowledged the possibility that, on remand, the district court could grant summary judgment for Merrell Dow if it found the *admissible expert testimony insufficient to raise a jury issue*. The Court stated: " . . . [E]ven if Dr. Done's epidemiology analysis is found to be admissible, the DeLucas are entitled to get to trial only if the district court is satisfied that this analysis

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[12] The *Ambrosini* Circuit Court Opinion is attached hereto as Appendix B. Citations to this Appendix will be designated (B ___).

together with any other evidence relevant to the causation issue would permit a jury finding that [plaintiff's] birth defects were, when measured against the appropriate burden of proof, caused by her mother's exposure to Bendectin." *Id.* at 959.

Despite Petitioners' studied blindness to the fundamental distinction between admissibility of evidence and sufficiency of evidence, there exists no inherent or court created conflict between FRCP 56 and FRE 704 and 705. The only conflict present in this case is the one between Petitioners' lack of evidence and the required burden of proof. Lacking *sufficient* evidence to meet this burden, Petitioners ask this Court to change the burden of proof to meet the evidence.

2. This Court Should Deny Certiorari Because The Sixth Circuit Correctly Applied The Standard For Summary Judgment Established By This Court.

Petitioners do not, nor can they, contend that the court below deviated from the summary judgment standard established by this Court in *Celotex Corporation v. Catrett*, 477 U.S. 317 (1986) and *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986). In those cases, this Court explicitly rejected the argument that the presence of any evidence, no matter how minimal, was sufficient to defeat a well pled motion for summary judgment. Rather, the lower courts were directed to answer the central question of "whether the evidence presents a *sufficient disagreement* to require submission to a jury or whether it is so *one-sided* that one party must prevail as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-252 (1986) (emphasis added). In rejecting the "scintilla" standard,

this Court restored summary judgment as a viable judicial tool for the early resolution of cases where one party could not present sufficient evidence to allow a reasonable jury to find in favor of that party.

Here, the Sixth Circuit correctly applied the summary judgment standard and after a full review of an extensive and detailed record, affirmed summary judgment for the Respondent. The Court of Appeals found that, although Petitioners had presented some evidence to support their claim, that evidence "could not lead a rational trier of fact to find for the [petitioners]." *Matsushita*, 475 U.S. at 587.

This case presents no issue of intercircuit conflict over the proper summary judgment standard, rather, this case presents only Petitioners' dissatisfaction with the adverse outcome resulting from the circuit court's well considered application of this Court's summary judgment standard. The Circuit Court did not, as Petitioners suggest, base its decision on the opinions of other courts which have ruled on summary judgment motions in other Bendectin cases. (A 7-21.) The Sixth Circuit in reviewing other Bendectin cases did note an inconsistency in results and attributed this inconsistency to a tendency to treat expert testimony with more deference than other testimony. In light of these inconsistent results, the Sixth Circuit urged courts to hold expert testimony to the *same* standards of reliability and sufficiency as other evidence. The "solution" involved no abuse of judicial power, no attack on the *Erie* doctrine, no imposition of some national tort law, and no creation of an *ad hoc* procedural device. The "solution" involved nothing more than the review of the evidence under the summary judgment standard consistently articulated by this Court. The Sixth

Circuit did not engage in unbridled judicial activism. To the contrary, the Sixth Circuit engaged in the exercise of judicial responsibility.

Petitioners ask nothing less than that this Court rewrite the Federal Rules of Evidence and the Federal Rules of Civil Procedure to carve out a unique place in the law for expert testimony. They would have this Court rule that, for expert testimony, there is no test for sufficiency but only blind and uncritical acceptance. Under such a new rule, summary judgment would be precluded *whenever* an expert is willing to testify to some factual position. Under Petitioners' theory of the law, courts would be compelled to accept an expert's opinion that the moon is made of cheese and further find that opinion sufficient to justify submission of the issue to a jury.

CONCLUSION

This Court should deny certiorari because Petitioners have failed to raise any issue for review which would have application beyond the confines of this solitary case. There has been no exceptional exercise of judicial activism by the circuit court. There has been no imposition of some universal federal Bendectin law. There has been no erosion of the boundaries drawn by the *Erie* doctrine.

What the Sixth Circuit has done, and what Petitioners wish this Court to undo, is apply this Court's well settled principles of summary judgment to the *unique* facts of this one case and find those facts insufficient to allow a reasonable jury to find in favor of Petitioners. Petitioners oppose that finding and ask this Court to again review

the factual record and again make a finding of facts – a task the lower courts have twice done before.

Petitioners' claims of inherent conflict between FRCP Rule 56 and FRE Rules 704 and 705 lack any basis in fact or law. In the absence of any issues of law that reach beyond this case, there is no policy for this Court to address and no purpose for review. Any decision rendered in this case would reach no further than these litigants.

For all of the aforementioned reasons, this Court should deny certiorari.

Respectfully submitted,

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APPENDIX B

Teresa AMBROSINI, et al., Appellants
v.
Jorge LABARRAQUE, M.D., et al., Appellees
No. 90-7146 and No. 90-7148
United States Court of Appeals,
District of Columbia Circuit
Argued January 24, 1992
Decided June 12, 1992

Appeal from the United States District Court for the District of Columbia.

Barry J. Nace, for appellants in 90-7146 and 90-7148.

David M. Covey, of the bar of the United States Court of Appeals for the State of New York, pro hac vice, by special leave of the Court, with whom John F. Mahoney was on the brief, for appellees, The Upjohn Company, in both cases.

Michael F. Flynn, Jr. and Katherine S. Duyer were on the brief, for appellee, Jorge Labarraque, in 90-7146 and 90-7148. James P. Gleason also entered an appearance for appellee.

Vincent H. Cohen and Walter A. Smith, Jr. entered appearances for appellee, Richardson-Merrell, Inc. in both cases.

Before: MIKVA, Chief Judge, RUTH B. GINSBURG and RANDOLPH, Circuit Judges.

MIKVA, Chief Judge:

*1 Escolastica and Bruno Ambrosini, on behalf of themselves and their daughter Teresa, appeal a decision

by the district court granting summary judgment in favor of defendants, The Upjohn Company and Dr. Jorge Labarraque. The district court held that the Ambrosinis failed to present specific, admissible scientific evidence sufficient to create a genuine issue of material fact on the issue whether the drug Depo-Provera caused the birth defects suffered by Teresa Ambrosini. The Ambrosinis argue that the district court erred in applying this court's earlier decision in Richardson v. Richardson-Merrell, Inc., 857 F.2d 823 (D.C. Cir. 1988), as well as Federal Rule of Evidence 703, in excluding their experts' affidavits. The Ambrosinis contend that the affidavits had a sufficient foundation under Rule 703 and contained the detail necessary to defeat the motion for summary judgment. Because we are convinced that the district court erred in applying the Richardson decision, as well as the standards governing summary judgment, we reverse the district court's grant of summary judgment as premature and remand for further proceedings.

I. BACKGROUND

Teresa Ambrosini suffers from severe birth defects including facial and ear malformations, hearing loss due to middle ear abnormalities, eye and vertebral malformations, and cleft lip and palate. The Ambrosinis brought an action against the manufacturers of the drugs Benedectin and Depo-Provera claiming that the drugs, either individually or in combination, caused Teresa's birth defects. The Ambrosinis also named as a defendant Mrs. Ambrosini's doctor, Dr. Jorge Labarraque, who prescribed the drugs. The claims against the manufacturer of Bendectin

were later dismissed leaving only Upjohn, the manufacturer of Depo-Provera, and Dr. Labarraque as defendants.

After preliminary discovery, Upjohn moved for summary judgment, contending that no reliable scientific evidence exists to support the contention that Depo-Provera caused Teresa's birth defects. In support of its motion, Upjohn submitted the affidavit of Dr. Joe Leigh Simpson who discussed three epidemiological studies, as well as other published articles and studies, all indicating that medroxyprogesterone (the chemical name for Depo-Provera) did not cause the type of birth defects suffered by Teresa Ambrosini.

In response to Upjohn's motion, the Ambrosinis submitted the affidavits of two expert physicians, Dr. Allen S. Goldman and Dr. Brian Strom. At the same time, the Ambrosinis moved to amend their list of experts provided under Federal Rule of Civil Procedure 26(b)(4) by replacing their previously named experts with Dr. Goldman and Dr. Strom. Although Upjohn opposed the switch, the district court did not rule on the Ambrosinis' motion and considered the experts' affidavits for the purpose of ruling on the summary judgment motion.

In his affidavit, Dr. Goldman stated, in relevant part, that: I am familiar with the available scientific and epidemiological data concern progestin and progesterone agents including the product manufactured by the defendant Upjohn Company known as Depo-Provera, and it is my opinion within a reasonable degree of medical and scientific certainty that Depo-Provera does cause severe and disfiguring birth defects of the type that is suffered by Teresa Ambrosini. It is further my opinion that within

a reasonable degree of medical certainty Teresa Ambrosini's birth defects were a result of the ingestion of Depo-Provera. *2 Dr. Goldman's affidavit did not, however, explain in detail the basis for his conclusion nor did it specifically state which studies, reports, or articles he relied on.

Dr. Strom stated in his affidavit that: It is my opinion that from a review of the epidemiological data that progestins, in general, do cause birth defects. This opinion is based upon the epidemiological data that is available in the literature. Further, in utilizing my education, training, and experience in the field I have used the same methodology that is generally and reasonably relied upon by epidemiologists and specifically those epidemiologists who interpret data involving drugs that are believed to cause birth defects. Dr. Strom's affidavit also did not identify the publications, studies, or methodology he used in forming his opinion.

After considering the affidavits submitted by both parties, the district court granted Upjohn's motion for summary judgment. The court reasoned that " "[p]laintiffs have failed to demonstrate that there are genuine issues of material fact or to identify admissible scientific evidence upon which a jury could find that Depo-Provera is a human teratogen.' ' Ambrosini v. Richardson-Merrell, Inc., et al., No. 84-3483, slip op. at 13 (August 31, 1990) (hereinafter Memorandum Opinion). The court interpreted our decision in Richardson v. Richardson-Merrell, Inc., 857 F.2d 823 (D.C. Cir. 1988), cert. denied, 110 S.Ct. 218 (1989) as requiring " "specific, admissible scientific proof' ' in support of a claim that a drug is responsible for causing birth defects. Memorandum Opinion, at 8.

The court held that the " "conclusory and unsupported' ' affidavits submitted by the experts were insufficient under Richardson, as well as under Rule 56 of the Federal Rules of Civil Procedure, to defeat Upjohn's motion for summary judgment. Memorandum Opinion at 12.

II. ANALYSIS

A. Expert Opinion Under Richardson.

We first address the district court's conclusion that summary judgment was proper under our decision in Richardson. Richardson addressed the admissiblity of expert testimony under Federal Rule of Evidence 703 which governs the basis for expert opinions. The Rule provides: The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence. FED. R. EVID. 703. Sometimes referred to as an " "expert testimony exception to the hearsay rule,' ' see e.g. United States v. Unruh, 855 F.2d 1363, 1376 (9th Cir. 1987), Rule 703 broadens the acceptable bases for expert testimony by allowing an expert to base an opinion on hearsay and other evidence not admissible in court. See Fed. R. Evid. 703 advisory committee's note; JACK B. WEINSTEIN & MARGARET A. BERGER, WEINSTEIN'S EVIDENCE P 703[01], at 6-7 (1991). Also, the Rule allows an expert to avoid the time consuming process of introducing otherwise admissible evidence that forms the basis for the expert's opinion. As

the advisory committee recognized: *3 [A] physician in his own practice bases his diagnosis on information from numerous sources and of considerable variety, including statements by patients and relatives, reports and opinions from nurses, technicians and other doctors, hospital records, and X rays. Most of them are admissible in evidence, but only with the expenditure of substantial time in producing and examining various authenticating witnesses. The physician makes life-and-death decisions in reliance on them. His validation, expertly performed and subject to cross-examination, ought to suffice for judicial purposes. FED. R. EVID. 703 advisory committee's note.

The expert testimony at issue in Richardson was a physician's opinion that the drug Bendectin caused the birth defects suffered by the plaintiffs' child. The expert, Dr. Alan K. Done, based his opinion on four types of evidence: (1) The chemical structure of Bendectin, (2) in vitro (test tube) studies, (3) in vivo (animal) studies, and (4) a reanalysis of the defendant's epidemiological studies showing no causal connection between the drug and the birth defects in question. Richardson, 857 F.2d at 826.

In his testimony, however, Dr. Done acknowledge that the chemical, in vitro, and in vivo studies alone could not form a sufficient basis to conclude that Bendectin caused birth defects. Id. And when confronted with epidemiological studies showing no statistically significant association between Bendectin and birth defects, Dr. Done conceded that he would not give an opinion as to causation unless epidemiological studies showed a statistically significant association between Bendectin and

birth defects. Id. at 831. Furthermore, while Dr. Done found a statistically significant association, he did so only by recalculating the data in studies that found none, and his recalculations were never published or subjected to peer review. Id.

Richardson rejected Dr. Done's opinion, therefore, because it lacked an adequate basis under Rule 703. The chemical, in vitro, and in vivo studies could not form a sufficient basis under Rule 703 because, as Dr. Done himself acknowledged, those studies were not of a type reasonably relied on by experts in the field to support a conclusion that Bendectin caused birth defects. Id. at 830. Because Dr. Done's recalculations of published epidemiological studies had never themselves been published or subject to peer review, we concluded that the recalculated epidemiological evidence also was insufficient to form an adequate scientific basis under Rule 703. Id. at 831.

In Ealy v. Richardson-Merrell, Inc., 897 F.2d 1159 (D.C. Cir. 1990), we reaffirmed our holding in Richardson. That Bendectin case involved the same chemical, in vitro, in vivo, and reanalyzed epidemiological data that was offered in Richardson, along with an additional in vivo study. Id. Once again, we held that the expert opinions were inadmissible because they lacked an adequate scientific basis under Rule 703. Id. at 1162. In effect, we took judicial notice of Richardson's conclusion that the chemical, in vitro, in vivo, and recalculated epidemiological studies were not of a type reasonably relied on by experts in the field. Richardson, we held, provided a " "binding legal precedent governing the admissibility of expert opinion on the ability of Bendectin to cause human birth defects.' ' Id. Because the experts in Ealy offered no

different bases for their opinions, we held that the opinions were inadmissible under Rule 703. Id. at 1163.

*4 Both Ealy and Richardson distinguished this court's earlier decision in Ferebee v. Chevron Chemical Co., 736 F.2d 1529 (D.C. Cir.), cert. denied, 469 U.S. 1062 (1984). The defendant in Ferebee argued that expert opinion that paraquat caused pulmonary fibrosis was inadmissible because it was too " "novel.' ' The defendant contended that, to be admissible, the expert opinion had to be generally accepted as reliable within the expert's field. Since there had never before been any evidence, nor any suggestion, that paraquat caused pulmonary fibrosis, the defendant argued that the evidence could not, at that point, be generally accepted in the scientific community. Id. at 1535.

The Ferebee court noted the difference between expert opinion based on controversial techniques or methods and expert opinion based on well-founded methods but which reaches a novel, and perhaps controversial, conclusion. Id. " "As long as the basic methodology employed to reach such a conclusion is sound,' ' the court held, " "[the] law does not preclude recovery until a "statistically significant' number of people have been injured or until science has the time and resources to complete sophisticated laboratory studies of the chemical.' ' Id. at 1536.

Ferebee, therefore, did not involve a challenge to the underlying basis or methods of an expert's opinion under Rule 703, as did Richardson and Ealy. In fact, the experts

in Ferebee relied on the " "same diagnostic methodology' ' in forming their opinions. Id. at 1535. Rather, Ferebee involved a challenge to the novelty of the expert's ultimate conclusion. Because both experts relied on accepted methods and data but reached different conclusions based on that information, the court held that it was " "a classic battle of the experts, a battle in which the jury must decide the victor.' ' Id. As we recognized in Richardson, " "[i]f experts are willing to testify to causation in such situations and their methodology is sound, the jury verdict should not be disturbed.' ' Richardson, 857 F.2d at 832 (emphasis added).

Four other Circuits have now reached conclusions similar to Richardson and Ealy in cases involving the drug Bendectin, although their reasoning has often differed. See Turpin v. Merrell Dow Pharmaceuticals, Inc., 959 F.2d 1349 (6th Cir. 1992) (finding expert testimony insufficient to support a finding that Bendectin caused plaintiff's birth defects); Daubert v. Merrell Dow Pharmaceuticals, Inc., 951 F.2d 1128 (9th Cir. 1991) (finding plaintiff's expert testimony inadmissible because reanalysis of peer-reviewed epidemiological studies is not a generally accepted scientific methodology); Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307, modified, 884 F.2d 166, reh'g denied, 884 F.2d 167 (5th Cir. 1989) (finding expert testimony insufficient to establish causation); Lynch v. Merrell-National Lab., Inc., 830 F.2d 1190 (1st Cir. 1987) (finding plainitff's [sic] expert testimony to be inadmissible because it lacked a proper foundation); see also DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941 (3rd Cir. 1990) (requiring the district court to

assess the reliability of the methodology of plaintiff's expert).

*5 In this case, the district court's reasons for granting summary judgment under Richardson are less than clear. At times it appears that the district court read Richardson as creating a heightened standard for causation in drug liability cases such as this one. The district court held that Richardson requires plaintiffs to bring forward " "specific, admissible scientific, admissible scientific proof in support of their claim that a drug is responsible for causing plaintiff's birth defects.' ' Memorandum Opinion, at 8. The court later noted as part of the basis for its grant of summary judgment that the affidavits submitted by the Ambrosinis' experts failed to set forth the facts and data underlying their opinions. Id. at 10. In other places, however, the district court seems to have assumed that the basis for the experts' opinions was the same as in Richardson, and rejected the opinions on that ground without mentioning Rule 703. Id. In any event, we think that the district court's holding reflects a misunderstanding of Richardson.

The Richardson court did not address the specificity with which an expert must state the basis for his opinion in an affidavit in response to a motion for summary judgment. Richardson held only that the chemical, in vitro, and in vivo studies relied on by the plaintiff's expert could not form an adequate basis for the conclusion that Bendectin caused the plaintiff's birth defects because the expert himself conceded that those studies alone would not reasonably be relied on by experts in the field. Richardson, 857 F.2d at 830. Furthermore, because the expert's reanalyzed epidemiological data had never

been published or subject to peer review, the opinion based on that reanalysis was inadmissible in the face of a wealth of published epidemiological studies that concluded to the contrary. Id. at 831. Nowhere in either Richardson or Ealy did we state that an expert's opinion (or an expert's affidavit in response to a motion for summary judgment) must specify the basis for the opinion to be admissible under Rule 703.

Indeed, such a holding would be contrary to Rule 705. That Rule provides: The expert may testify in terms of opinion or inference and give reasons therefor without prior disclosure of the underlying facts or data, unless the court requires otherwise. The expert may in any event be required to disclose the underlying facts or data on cross-examination. FED. R. EVID. 705. Rule 705 eliminates the prior practice of requiring an expert to set out, specifically, the facts and data underlying an opinion before allowing the expert to testify. See JACK B. WEINSTEIN & MARGARET A BERGER, WEINSTEIN'S EVIDENCE P 705[01], at 5-6 (1991). Under Rule 705, an expert's affidavit, no matter what the basis, cannot be excluded solely because it fails to disclose the facts or data underlying the opinion.

The Ambrosinis responded to Upjohn's motion for summary judgment by offering the affidavits of two experts: Dr. Strom, who concluded that progestins, in general, cause birth defects, and Dr. Goldman who concluded, more specifically, that Depo-Provera caused Teresa Ambrosini's birth defects. At that point, pursuant to Rule 705, the court could have required Dr. Strom and Dr. Goldman to disclose the basis for their opinions so that it could determine whether the opinions had an adequate

foundation (i.e. whether they were based on information that experts in the field would reasonably rely on in determining whether a particular drug causes birth defects). Only then could the court determine whether the affidavits were admissible under Rule 703. A court must know the basis for an expert's opinion before it can determine that the basis is not of a type reasonably relied on by experts in the field. See e.g. In re Paoli R.R. Yard PCB Litigation, 916 F.2d 829, 854-55 (3d Cir. 1990). Because the court below never delved further into the basis for the expert opinions, particularly the one supplied by Doctor Goldman, see infra pp. 13-14, we are persuaded that the court acted prematurely in granting summary judgment on the basis of Richardson.

*6 Upjohn would have us read the Richardson decision more broadly, arguing that Richardson did more than rule on the admissibility of expert opinion under Rule 703. Upjohn contends that Richardson upheld the district court's decision to issue a j.n.o.v. because expert conclusions based on chemical, in vitro, in vivo, and unpublished recalculations of epidemiological data do not provide " "sufficient evidence upon which a jury could properly base a verdict for the plaintiff.' ' But Richardson did not hold that chemical, in vitro, and in vivo studies would be insufficient, in all cases, to support a conclusion that particular drug causes birth defects. Richardson held only that Dr. Done's testimony was inadmissible under Rule 703 because he acknowledged that the data underlying his opinion was not of a type reasonably relied on by experts in the field. And because the court found that, without that evidence, no reasonable jury could find for the plaintiff, it upheld the district

court's decision to grant a j.n.o.v.. See Richardson, 857 F.2d at 833.

The distinction we draw between this case and Richardson is not a minor one. When a court denies the right to have a jury decide a disputed issue, especially one of a scientific nature, its reasons for doing so must be strong. See Ferebee, 736 F.2d at 1535 (expert opinion based on sound scientific methodology presents " "a classic battle of the experts, a battle in which the jury must decide the victor' '). Science is a rapidly changing field. Methodologies rejected today may be universally accepted in the future. DNA evidence as a method of identification, for example, was virtually unheard of 25 years ago but is gaining widespread acceptance in the courts today. See Comment, Trial By Certainty: Implications of Genetic " "DNA Fingerprints' ', 39 EMORY L. J. 309 (1990) (citing State v. Andrews, 533 So.2d 841 (Fla. Dist. Ct. App. 1988) as the first case in the United States accepting DNA evidence). Our decisions must leave the way open for these changes.

Upjohn makes much of the fact that the record in this case is the same as the record that this court considered when it affirmed the district court's decision to grant summary judgment to Merrell-Dow, Upjohn's former co-defendant in this case. We point out, however, that the district court granted Merrell-Dow's motion for summary judgment only after issuing an Order to Show Cause requiring plaintiffs to identify a basis, admissible under Rule 703 and Richardson, for their expert's opinion that Bendectin caused Teresa's birth defects. See Koller v. Richardson-Merrell, Inc., No. 80-1258, slip op. at 2 (D.D.C. June 30, 1989), amended sub nom. Ambrosini v.

Richardson-Merrell, Inc., No. 86-0278 (D.D.C. July 12, 1989), aff'd, No. 90-7148 (D.C. Cir. 1990). Only after the Ambrosinis failed to identify a basis for their expert's opinion other than the chemical, in vitro, in vivo, and reanalyzed epidemiological data rejected in Richardson did the court grant Merrell-Dow's motion for summary judgment. Id. at 8. This is precisely the sort of injury the court must undertake before determining whether expert testimony has an adequate foundation under Rule 703. No show cause order was issued in this case before the district court granted Upjohn's motion.

B. The Standards for Summary Judgment Under Rule 56.

*7 Our inquiry does not end with the determination that the district court erred in granting summary judgment on the basis of this court's decision in Richardson, for even if the expert affidavits were admissible under Rule 703, summary judgment would have been proper if the affidavits were not sufficient to create a genuine issue of material fact. This court, as well as others, has recognized that the issue of admissibility of an expert's opinion under Rules 703 and 705 is separate and distinct from the issue whether the testimony is sufficient to withstand a motion for summary judgment under Rule 56. See Merit Motors, Inc. v. Chrysler Corp., 569 F.2d 666, 673 (D.C. Cir. 1977); Monks v. General Elec. Corp., 919 F.2d 1189, 1192-93 (6th Cir. 1990); Mid-State Fertilizer Co. v. Exchange Nat'l Bank of Chicago, 877 F.2d 1333, 1339 (7th Cir. 1989); Evers v. General Motors Corp., 770 F.2d 984,

986 (11th Cir. 1985); United States v. Various Slot Machines on Guam, 658 F.2d 697, 700-701 (9th Cir. 1981).

Rule 56(e) of the Federal Rules of Civil Procedure states that, in order to defeat a well-supported motion for summary judgment an affidavit in response to the motion " "must set forth specific facts showing that there is a genuine issue for trial.' ' FED. R. CIV. P. 56(e) (emphasis added). Upjohn insists, and the district court apparently would agree, that because the affidavits of Doctors Strom and Goldman do not set forth the " "specific facts' ' or reasoning behind their opinions, they are insufficient, under Rule 56(e), to defeat the motion for summary judgment. See Memorandum Opinion, at 12.

In support of its contention, Upjohn cites to a number of cases, including this court's decision in Merit Motors. But in Merit Motors we did not uphold the district court's grant of summary judgment because the expert failed to identify the basis for his opinion. Rather, we upheld summary judgment because the district court correctly determined that the plaintiff's expert was unfamiliar with the record in the case and because the expert's opinion was based on speculations and hypotheses that were contradicted by his own deposition testimony. See Merit Motors, 569 F.2d at 672; see also Monks v. General Elec. Co., 919 F.2d at 1192 (standard articulated in Merit Motors is that affidavits by experts who are unfamiliar with the record are insufficient to withstand summary judgment). The other cases that Upjohn cites are similarly distinguishable.

Dr. Goldman's affidavit stated a specific fact, namely that, based on " "the available scientific and epidemiological data concerning progestin and progesterone agents including the product manufactured by the defendant Upjohn Company known as Depo-Provera,' ' as well as a review of relevant medical records of Mrs. Ambrosini and her daughter Teresa, Depo-Provera caused Teresa Ambrosini's birth defects. We are convinced that, if admissible, Dr. Goldman's affidavit gave a sufficient factual basis to defeat summary judgment at this point. We need not decide the more difficult question whether Rule 56 would be satisfied by the bare conclusion that Depo-Provera caused Teresa's birth defects. See Bulthuis v. Rexall Corp., 789 F.2d 1315 (9th Cir. 1985) (distinguishing between an affidavit that fails to state any basis for its opinion and an affidavit that discloses the general basis for its opinion but fails to explain, in detail, how the opinion was reached). Nor need we decide whether Dr. Strom's affidavit, which concluded only that progestins cause birth defects in general, could defeat summary judgment even at the outset in this case.

CONCLUSION

*8 Without a further inquiry into the factual basis for the opinion of Doctors Goldman and Strom, the district court erred in granting summary judgment based on this court's decision in Richardson. And because Dr. Goldman's affidavit set forth a specific fact, we are persuaded that, if admissible, it was enough to defeat Upjohn's motion for summary judgment. We reverse the district court's order granting summary judgment in favor of Upjohn, therefore, and remand for further proceedings

consistent with this opinion. Because the district court based its grant of summary judgment in favor of Dr. Labarraque on the same grounds, we also reverse the grant of summary judgment with respect to Dr. Labarraque. On remand, it will remain open to the district court to address the defendants' opposition to the plaintiffs' untimely substitution of Doctors Strom and Goldman in their Rule 26(b)(4) list.

Reversed and remanded.

C.A.D.C., 1992.